TITLE 3. FOOD AND AGRICULTURE
DIVISION 5. LIVESTOCK DRUGS
CHAPTER 1. SALES OF RESTRICTED LIVESTOCK DRUGS
CHAPTER 2. SALES OF CALIFORNIA PRESCRIPTION DRUGS

NOTICE OF MODIFICATIONS TO THE TEXT OF PROPOSED REGULATIONS

NOTICE IS HEREBY GIVEN that pursuant to the requirements of Government Code subsection 11346.8(c) and section 44 of Title 1 of the California Code of Regulations (CCR), the California Department of Food and Agriculture (Department), is providing notice of changes made to the action described in the Informative Digest published in the California Regulatory Notice Register on July 7, 2017 [Notice File No. Z2017-0627-01, Register 2017, No. 27-Z] relating to sales of restricted livestock drugs and California prescription drugs. These changes are in response to comments received regarding the proposed regulation.

The Department is proposing to modify the originally proposed text for Chapter 1 and Chapter of Title 3, Division 5 of the CCR. The Department will continue the regulation process with the previously proposed regulation text, unless noted within the newly modified text.

The 45-day public comment period for the originally proposed text for this proposal began July 7, 2017 and ended at 5:00 p.m. on August 22, 2017. Two public hearings on the originally proposed text were held; the first on August 15, 2017 and the second on August 22, 2017. A 30-day public comment period for the revised proposed text for this proposal began February 20, 2018 and ended at 5:00 p.m. on March 22, 2018. A public hearing on the revised proposed text was held on March 19, 2018. The Department is now publishing a notice of a 15-day comment period on the revised proposed text. The purpose is to allow interested persons time to review the modifications to the proposed text and submit written comments. The 15-day public comment period begins **June 14, 2018 and ends at 5:00 p.m. on June 29, 2018.**

Please note: Any written comments are to be restricted to the recent modifications as indicated in *double underline italic*, ~~underline double strikethrough~~, and ~~double underline double strikethrough~~ within the enclosed language. The Department is not required to respond to comments received in response to this notice on other aspects of the proposed regulation.

WRITTEN COMMENT PERIOD

The Department will accept written comments regarding the newly proposed changes between **June 14, 2018** and **June 29, 2018**. Comments may be submitted by mail to the address provided below, by facsimile (FAX) to (916) 900−5349, or by email to aus_regulations@cdfa.ca.gov. The written comment period closes at **5:00 p.m. on June 29, 2018**. The Department will only consider comments received at the Department by that time.

Submit comments to:

Rachelle Kennedy, Senior Environmental Scientist (Specialist)
Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch
California Department of Food and Agriculture
1220 N Street, Sacramento, CA 95814

All written comments received by **5:00 p.m. on June 29, 2018** which pertain to the newly indicated changes will be reviewed and responded to by the Department in the Final Statement

of Reasons as part of the compilation of the rulemaking file. Please limit your comments to the newly proposed modifications to the text.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of materials regarding this proposal can be accessed through the Department's website: https://www.cdfa.ca.gov/is/Regulations.html.

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

MODIFIED REGULATION TEXT

Original proposed text is displayed in underline type.

Proposed additions for the 30-day comment period are displayed in double underline type. Proposed deletions for the 30-day comment period are displayed in ~~underline strikethrough~~ type.

Proposed additions for the 15-day comment period are displayed in *double underline italic* type. Proposed deletions for the 15-day comment period are displayed in ~~underline double strikethrough~~ and ~~double underline double strikethrough~~ type.

CALIFORNIA CODE OF REGULATIONS
TITLE 3. FOOD AND AGRICULTURE
DIVISION 5. LIVESTOCK DRUGS
CHAPTER 1. SALES OF RESTRICTED LIVESTOCK DRUGS

ARTICLE 1. DEFINITIONS

§5000. Definitions.
For purposes of this chapter, the following definitions apply:

(a) "Company representative" ~~"Designated individual"~~ means an individual representing a restricted livestock drug licensee that is assigned to perform the duties required to maintain a restricted livestock drug licensee's compliance with California livestock drug laws and regulations.

(b) "Livestock" includes all animals*, poultry, and bees, and aquatic and amphibian species* ~~in a species typically~~ *which are* raised, kept, or used for profit ~~and includes bees, mammals, avian, aquatic, and amphibian species~~. It does not include those species which are usually kept as pets, such as dogs, cats, and pet birds. "Species ~~that~~ *which* are raised, kept, or used for profit" means:

(1) Livestock that are ~~typically~~ used for financial gain, commercial use, breeding, competition, or show; or

(2) Livestock whose owners are engaged in business using animals for financial gain, commercial use, breeding, competition, or show.

(c) "Parent company" means the legal business entity that owns a restricted livestock drug licensee.

(d) "Qualified individual" means a person who meets ~~all of the necessary~~ *the* requirements ~~in order to sell California prescription drugs under~~ *of* Section 5009 of Title 3 of the California Code of Regulations.

(e ~~c~~) “Restricted livestock drug” means any livestock drug which is sold in such form that it might be administered to humans and if so administered would be dangerous to the health of such humans or any livestock drug which if improperly administered to livestock is dangerous to the health of such livestock or to humans who consume products from such livestock. Restricted drugs include all of the following:

(1) Arsenic compounds and preparations~~,~~;

(2) Diethylstilbestrol and other substances which have a hormonelike action~~,~~;

(3) Sulfanilamide or substitute sulfanilamides~~.~~;

~~(4) Antibiotic preparations, including medically important antimicrobial drugs as defined in Section 14400(a) of Chapter 4.5 of Division 7 of the Food and Agricultural Code.~~

~~(5) Such other drugs and their preparations which the Secretary determines are hazardous to the health of livestock or the public safety.~~

(4) Antibiotic preparations, including those medically important antimicrobial drugs federally labeled for over the counter sale listed in Appendix A of the federal Food and Drug Administration’s Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended~~,~~;

(5) Type A Medicated Articles as defined in Section 558.3(b)(2) of Title 21 of the Code of Federal Regulations *(4-1-18), which is hereby incorporated by reference*~~,~~*; and*

(6) Any drug that has a withdrawal period.

~~(d) “Restricted livestock drug licensee” is a person that has obtained a restricted livestock drug license pursuant to Article 5 (commencing with Section 14321) of Chapter 4 of Division 7 of the Food and Agricultural Code.~~

(f) “Restricted livestock drug licensee” is a location licensed pursuant to *Article 3 of Chapter 1 of Division 5 of Title 3 of the California Code of Regulations* ~~Article 5 (commencing with Section 14321) of Chapter 4 of Division 7 of the Food and Agricultural Code~~ where sales of restricted livestock drugs occur.

Note: Authority Cited: Sections 407 and 14231~~,~~ ~~of the~~ Food and Agricultural Code. Reference: Section~~s~~ 14203, 14205~~,~~ *and* 14321~~,~~ ~~of the~~ Food and Agricultural Code.

ARTICLE 2. GENERAL PROVISIONS

§5001. Sales of Restricted Livestock Drugs.

~~(a) A person shall not sell any restricted livestock drug in this state at retail unless he or she holds a restricted livestock drug license issued pursuant to Article 5 of Chapter 4 of Division 7 of the Food and Agricultural Code.~~

~~(1) The term sell includes in-person sales at a physical place of business, including mobile units, as well as all sales conducted using the internet, electronic mail, telephone, facsimile, mail order, or catalog.~~

(2) A person whose business is located outside of the state of California who makes any sale of a restricted livestock drug into California must obtain a restricted livestock drug license prior to any such sale.

(3) A separate restricted livestock drug license is required for each place of business at which any restricted livestock drug is kept for sale, and for each mobile unit in which any such drug is kept for sale.

(b) A copy of the laws and regulations relating to livestock drugs shall be provided to each restricted livestock drug licensee upon issuance of the license. The failure of any restricted livestock drug licensee to receive a copy of the regulations is not a defense to a violation of the regulations.

(c) Each restricted livestock drug licensee shall be supervised or managed by a designated individual named on the restricted livestock drug license application that shall be responsible for maintaining the restricted livestock drug licensee's compliance with state laws and regulations.

(a) A restricted livestock drug shall only be sold at retail within or into this state by a restricted livestock drug licensee. This includes:

(1) In-person sales at a physical place of business, including mobile units~~.~~ *and*

(2) All sales conducted using the internet, electronic mail, telephone, facsimile, mail order, or catalog.

(b) A business located outside of the state of California that makes any retail sale of a restricted livestock drug into this state shall obtain a restricted livestock drug license prior to any such sale.

(c) A separate restricted livestock drug license is required for each place of business at which any restricted livestock drug is kept for sale, and for each mobile unit in which any such drug is kept for sale.

(d) All livestock drugs sold by restricted livestock drug licensees must be registered pursuant to ~~Article 4 of Chapter 4 of Division 7~~ *Section 14281* of the Food and Agricultural Code.

Note: Authority Cited: Sections 407 and 14231, ~~of the~~ Food and Agricultural Code. Reference: Sections 14281, 14321 and 14326, ~~of the~~ Food and Agricultural Code.

ARTICLE 3. LICENSING

§5002. License Application.

(a) Any person may file with the Secretary an application for a restricted livestock drug license pursuant to Article 5 of Chapter 4 of Division 7 of the Food and Agricultural Code. The application shall be on a form which is supplied by the Secretary and shall contain:

(1) The legal business name, Federal Tax ID number, and telephone number of the firm.

(2) The full name of the owner or owners of the firm.

(3) The mailing address of the firm, including street number, city, county, state, and ZIP code.

(4) The location of business to be licensed, including street number, city, county, state, and ZIP code. If the business to be licensed is conducting online sales, the website where sales are conducted shall be provided.

(5) A designated individual for the business to be licensed who shall be responsible for compliance with the livestock drugs law and shall serve as the primary emergency contact. The following information shall be provided for the designated individual: name, title, email address, and telephone number.

(6) A secondary emergency contact for the business to be licensed. The following information shall be provided for the secondary emergency contact: name, title, email address, and telephone number.

(7) A disclosure of whether the business to be licensed is a mobile unit. If the location to be licensed is a mobile unit, the license plate number shall be provided.

(8) A disclosure of the company type (corporation, partnership, individual, limited liability company, co-partnership, or other). If other, the type shall be specified.

(9) A disclosure of the type of sales conducted by the business to be licensed (sales directly to the end user for the purpose of administration to livestock and/or sales to other businesses for the purpose of resale).

(10) A disclosure of whether the business to be licensed will sell medically important antimicrobial drugs as defined in Section 14400(a) of Chapter 4.5 of Division 7 of the Food and Agricultural Code.

(11) A certification that the information provided on the application is complete, true, and accurate. The certification shall be made by the owner of the firm or designated individual for the business to be licensed and shall contain the following information: name, title, signature, and date signed.

(b) The application shall be accompanied by an application fee of fifty dollars ($50).

(1) The fee is not refundable if the license is refused.

(2) If the license is issued, the application fee covers the license for the remainder of the current calendar year in which it is issued.

(3) The fee shall not be reduced to cover a fraction of a year.

(c) The application described in Section 5002(a) and accompanying fee described in Section 5002(b) shall be submitted in one of two ways:

(1) Electronically using the Feed, Fertilizer, and Livestock Drugs Regulatory Services online registration database.

~~(2) By mail using a form available on the Feed, Fertilizer, and Livestock Drugs Regulatory Services website.~~

~~(d) A restricted livestock drug licensee shall notify the Department within thirty (30) calendar days if any of the information provided on the license application changes after the license is issued.~~

(a) The restricted livestock drug license application required pursuant to ~~Article 5 of Chapter 4 of Division 7~~ *Section 14322* of the Food and Agricultural Code shall contain:

(1) The following information for the parent company:

(A) The legal business name, Federal Tax ID number, and telephone number.

(B) The full *legal* name of the owner or owners.

(C) The mailing address, including street number, city, county, state, and ZIP code.

(D) ~~Identification of t~~*T*he company representative who shall be responsible for compliance with the livestock drugs law and regulations. This person shall serve as the Department's primary point of contact for the parent company. The following information shall be provided *for the company representative*: *full legal* name, title, email address, and telephone number.

(E) The ~~company~~ type *of entity* (corporation, partnership, ~~individual~~ *sole proprietorship*, limited liability company, co-partnership, or other). If other, the type shall be specified.

(2) The following information for the location to be licensed:

(A) The physical location where the sale of restricted livestock drugs will occur, including street number, city, county, state, and ZIP code.

(B) Whether the location to be licensed conducts online sales. If the location *to be licensed* ~~is conducts~~*ing* online sales, the website where sales are conducted shall be provided.

(C) ~~Identification of t~~*T*he manager for the location to be licensed. This person shall serve as the Department's primary point of contact for the location to be licensed. The following information shall be provided *for the manager*: *full legal* name, title, email address, and telephone number.

(D) Whether the location to be licensed is a mobile unit. If the location to be licensed is a mobile unit, the license plate number shall be provided.

(E) Whether the location to be licensed conducts sales of restricted livestock drugs to other businesses for the purpose of resale.

(F) Whether the business to be licensed intends to sell California prescription drugs as defined in Section 5007(a) of Title 3 of the California Code of Regulations. Retailers that indicate such intent shall comply with all requirements of Chapter 2 of Division 5 of Title 3 of the California Code of Regulations and shall submit all of the following:

(i) The full legal name of each qualified individual that will sell California prescription drugs and documentation that each individual identified meets the requirements of Section 5009 of Title 3 of the California Code of Regulations.

(ii) Either a written certification from a consulting pharmacist pursuant to Section ~~5011(b)~~ *5013(b)* of Title 3 of the California Code of Regulations, signed and dated within three (3) months from the date of application; or identification of a staff pharmacist pursuant to Section ~~5011(c)~~ *5013(c)* of Title 3 of the California Code of Regulations.

(3) The *full legal* name and title of the individual submitting the application and either their signature and the date signed or electronic acknowledgment of submission affirming that the information provided on the application is complete, true, and accurate.

(b) The application shall be accompanied by a non-refundable application fee of fifty dollars ($50). The fee shall not be reduced to cover a fraction of a year.

(c) A restricted livestock drug license is valid for the remainder of the current calendar year in which it is issued.

(d) A restricted livestock drug licensee shall notify the Department within thirty (30) calendar days if any of the information provided pursuant to Sections 5002(a)(1) through 5002(a)(2)(E) changes after the license is issued.

(e) A restricted livestock drug licensee shall notify the Department if any information provided pursuant to Section 5002(a)(2)(F) changes after the license is issued. This information shall be provided to the Department before a qualified individual may sell any California prescription drug as defined in Section 5007(a) of Title 3 of the California Code of Regulations.

(f) A restricted livestock drug license application ~~may~~ *shall* be denied if ~~prior enforcement actions have been taken against~~ *two or more violations has been issued to* the applicant, owner(s) listed, parent company, or the location to be licensed *within the previous twelve (12) months*.

Note: Authority Cited: Sections 407 and 14231, ~~of the~~ Food and Agricultural Code. Reference: Sections 14322, 14323~~,~~ and 14324, ~~of the~~ Food and Agricultural Code. ~~Section 4198 of the Business and Professions Code. Section 1780 of Title 16 of the California Code of Regulations.~~

§5003. License Renewal.

~~(a) Applications for restricted livestock drug license renewal shall be submitted on or before January 31 of each year on a form supplied by the Secretary which shall be limited to the information described in Section 5002(a) of this chapter.~~

~~(b) The fee for the renewal application for a license is fifty dollars ($50) per year, payable on or before January 31 of each year. If the fee is not paid by that date, a penalty of fifty dollars ($50) shall be added to the fee.~~

~~(c) Renewal applications and accompanying fees shall be submitted in the manner specified in Section 5002(c) of this chapter.~~

~~(d) A restricted livestock drug licensee shall notify the Department in a timely manner if any of the information provided on the license renewal changes after the license is renewed.~~

(a) Applications for restricted livestock drug license renewal shall be submitted *between* ~~beginning~~ January 1 and ~~on or before~~ January 31 of each year and shall be limited to the information described in Section 5002(a) of this chapter.

(b) The fee for the renewal application for a license is fifty dollars ($50) per year, payable on or before January 31 of each year. If the fee is not paid by that date, a penalty of fifty dollars ($50) shall be added to the fee.

(c) Any *restricted livestock drug licensee* ~~location~~ that fails to renew *its* ~~their~~ license on or before January 31 shall not sell restricted livestock drugs beginning February 1. *Restricted livestock drugs shall not be sold by the restricted livestock drug licensee* until ~~the location has renewed their~~ *the license has been renewed by* ~~with~~ the ~~d~~*D*epartment.

(d) A restricted livestock drug licensee shall notify the Department within thirty (30) calendar days if any of the information provided pursuant to Sections 5002(a)(1) through 5002(a)(2)(E) changes after the license is renewed.

(e) A restricted livestock drug licensee shall notify the Department if any information provided pursuant to Section 5002(a)(2)(F) changes after the license is renewed. This information shall be provided to the Department before a qualified individual may sell any California prescription drug as defined in Section 5007(a) of Title 3 of the California Code of Regulations.

(f) A restricted livestock drug license renewal application ~~may~~ *shall* be denied if ~~prior enforcement actions have been taken against~~ *two or more violations has been issued to* the applicant, owner(s) listed, parent company, or the location to be licensed *within the previous twelve (12) months*.

Note: Authority Cited: Sections 407 and 14231~~, of the~~ Food and Agricultural Code. Reference: Sections 14322 and 14325~~, of the~~ Food and Agricultural Code.

ARTICLE 4. RECORDKEEPING

§5004. Sales Records.

(a) Each restricted livestock drug licensee shall maintain ~~in this state, or with the Secretary's permission, at another~~, at the licensed location, a~~n accurate~~ record of each sale of a restricted livestock drug by the licensee.

(b) The record of each sale of a restricted livestock drug shall include all of the following:

(1) The established drug name or trade name, route of administration, quantity, and lot number(s) of the restricted livestock drug sold~~,~~*;*

(2) Date of sale~~,~~*;*

(3) Name, address, *and* telephone number~~, and email address (optional)~~ of the purchaser~~,~~*;*

(4) Signature of the purchaser or an electronic acknowledgment of sale~~,~~*; and*

(5) Any additional information as required under Section 5010(c)*(1)* ~~5008~~ of the California Code of Regulations regarding retail sales of ~~medically important antimicrobial drugs~~ California prescription drugs.

~~(c) The record of each sale of a restricted livestock drug shall be kept by a restricted livestock drug licensee for a period of not less than three years following the transaction.~~

~~(d) The record of each sale of a restricted livestock drug is subject to audit by the Secretary and shall be made available to the Secretary upon request.~~

(c) The record of each sale of a restricted livestock drug:

(1) Shall be retained for a period of not less than three (3) years following the ~~transaction~~ *date of sale.*

(2) Is subject to audit by the *Department* ~~Secretary~~ and shall be made available to the *Department* ~~Secretary~~ upon request.

Note: Authority Cited: Sections 407 and 14231, ~~and of the~~ Food and Agricultural Code. Reference: Sections 14295, 14327, 14328, 14329, ~~,~~ and 14330, ~~of the~~ Food and Agricultural Code.

ARTICLE 5. VIOLATIONS AND PENALTIES

§5005. Violations.

(a) It is unlawful for any business located within or outside of the ~~s~~State of California to make any retail sale of a restricted livestock drug within or into this state unless the business holds a valid restricted livestock drug license *issued pursuant to Article 3 of Chapter 1 of Division 5 of Title 3 of the California Code of Regulations* ~~under Article 5 of Chapter 4 of Division 7 of the Food and Agricultural Code~~.

(b) It is unlawful for any business to fail to obtain a separate restricted livestock drug license for each place of business at which any restricted livestock drug is kept for sale, and for each mobile unit in which any such drug is kept for sale.

(c) It is unlawful for any *business* ~~restricted livestock drug licensee~~ to sell a livestock drug that is not registered pursuant to Article 4 of Chapter 4 of Division 7 of the Food and Agricultural Code.

(d) It is unlawful for any *applicant* ~~business~~ to submit inaccurate or outdated information on the restricted livestock drug license application or renewal.

(e) It is unlawful for any restricted livestock drug licensee to fail to notify the Department within thirty (30) calendar days if any of the information provided pursuant to Sections 5002(a)(1) through 5002(a)(2)(E) changes after the license is issued.

(f) It is unlawful for any restricted livestock drug licensee to sell a California prescription drug prior to providing the information required pursuant to Section 5002(a)(2)(F).

(g) It is unlawful for any restricted livestock drug licensee to fail to notify the Department prior to selling a California prescription drug if any of the information provided pursuant to Section 5002(a)(2)(F) changes after the license is issued.

(h) It is unlawful for any restricted livestock drug licensee to fail to keep ~~adequate~~ sales records of restricted livestock drugs or to fail to make the required records available to the ~~Secretary~~ *Department* upon request as required by Section 5004 of this chapter.

(i) It is unlawful for any *business* ~~restricted livestock drug licensee~~ to prevent the entry into and inspection of any premises where restricted livestock drugs are stored or sold.

(j) It is unlawful for any *business* ~~restricted livestock drug licensee~~ to sell any restricted livestock drug that is outdated, damaged, deteriorated, misbranded or adulterated.

(k) It is unlawful for a *restricted livestock drug licensee* ~~location~~ who does not renew their license with the ~~d~~*D*epartment on or before January 31 to sell any restricted livestock drugs beginning February 1 of that year.

Note: Authority Cited: Sections 407 and 14231, ~~and of the~~ Food and Agricultural Code. Reference: Sections 14321, 14326, 14327, 14328, 14329, 14351, 14354, 14356, 14357, and 14362, ~~of the~~ Food and Agricultural Code.

§5006. Penalties.

(a) Upon finding a violation, the ~~Secretary~~ *Department* ~~may~~ shall issue a notice of warning *in accordance with Section 14382 Food and Agricultural Code*.

(b) A first violation of this chapter is an infraction punishable by a fine of ~~500~~ *five hundred* dollars ($500).

(c) A second or subsequent violation of this chapter is a misdemeanor punishable by a fine of ~~1000~~ *one thousand* dollars ($1000).

~~(d) A person may contest a fine for any violation specified in Section 5006 by requesting an informal hearing. At the hearing, the person shall be given the right to present evidence on his or her own behalf.~~

~~(1) Requests must be submitted by written correspondence to the Department of Food and Agriculture Legal Office of Hearings and Appeals, 1220 "N" Street, Suite 315, Sacramento, California 95814.~~

~~(2) Requests must be submitted within 30 days from the date the notice of fine was signed by investigator and person notified.~~

~~(3) If a hearing is not requested, the fine shall constitute a final, non-reviewable order.~~

~~(e)~~ *(d)* If the renewal fee is not paid by January 31, a penalty of fifty dollars ($50) shall be added to the license fee.

Note: Authority Cited: Sections 407 and 14231, ~~and of the~~ Food and Agricultural Code. Reference: Sections 14381 and 14382, ~~of the~~ Food and Agricultural Code; ~~. Chapter 4.5 (commending with Section 11400) and Chapter 5 (commencing with Section 11500)~~ Sections *11445.20, 11445.30, 11445.40, 11445.50 and 11445.60,* ~~of the~~ Government Code.

CALIFORNIA CODE OF REGULATIONS
TITLE 3. FOOD AND AGRICULTURE
DIVISION 5. LIVESTOCK DRUGS
CHAPTER 2. SALES OF ~~MEDICALLY IMPORTANT ANTIMICROBIAL~~ CALIFORNIA PRESCRIPTION DRUGS

ARTICLE 1. DEFINITIONS

§5007 ~~5005~~. Definitions.
For purposes of this chapter, the following definitions apply:

~~(a) "Dispense" means to deliver a medically important antimicrobial drug to a purchaser under a lawful veterinary prescription or veterinary feed directive.~~

(a) "California prescription drug" means a medically important antimicrobial drug intended for use on livestock that is federally labeled for over the counter sale but requires a prescription to be sold in California pursuant to Chapter 4.5 of Division 7 of the Food and Agricultural Code.

(b) "Extra label use" ~~has the same definition as in Section 530.3(a) of Title 21 of the Code of Federal Regulations.~~ means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

~~(c) "Inventory" means a record of accountability for all medically important antimicrobial drugs.~~

(c) "Federal prescription drug" means a drug intended for use on livestock that is labeled with the statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(d) "Livestock" includes all animals ~~in a species typically~~ *and poultry, including aquatic and amphibian species, that are* raised, kept, or used for profit ~~and includes mammals, avian, aquatic, and amphibian species. It~~ *Livestock* does not include *bees or* those species which are usually kept as pets, such as dogs, cats, and pet birds. "Species that are raised, kept, or used for profit" means:

(1) Livestock that are ~~typically~~ used for financial gain, commercial use, breeding, competition, or show; or

(2) Livestock whose owners are engaged in business using animals for financial gain, commercial use, breeding, competition, or show.

(e) "Medically important antimicrobial drug" means ~~a restricted livestock drug as defined in Section 14400(a) of Chapter 4.5 of Division 7 of the Food and Agricultural Code.~~ an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

(f) “Pharmacist” means a natural person to whom a license has been issued by the State Board of Pharmacy~~,~~ under Section 4200 of the Business and Professions Code.

(g) “Prescription” means an oral, written, or ~~electronic transmission~~ *email* order issued by a veterinarian that includes the following information:

(1) The name and address of the livestock owner;

(2) The name and quantity of the drug or device prescribed and the directions for use;

(3) The date of issue;

(4) The name, address, and telephone number of the prescribing veterinarian, and;

(5) If in writing, the signature of the prescribing veterinarian.

(h) “Qualified individual” means a person who meets ~~all of the necessary~~ *the* requirements ~~in order to sell California prescription drugs under~~ *of* Section 5009 of Title 3 of the California Code of Regulations.

(i ~~f~~) “Restricted livestock drug” means any livestock drug which is sold in such form that it might be administered to humans and if so administered would be dangerous to the health of such humans or any livestock drug which if improperly administered to livestock is dangerous to the health of such livestock or to humans who consume products from such livestock. Restricted drugs include all of the following:

(1) Arsenic compounds and preparations~~,~~*;*

(2) Diethylstilbestrol and other substances which have a hormonelike action~~,~~*;*

(3) Sulfanilamide or substitute sulfanilamides~~,~~*;*

~~(4) Antibiotic preparations, including medically important antimicrobial drugs as defined in Section 14400(a) of Chapter 4.5 of Division 7 of the Food and Agricultural Code.~~
~~(5) Such other drugs and their preparations which the Secretary determines are hazardous to the health of livestock or the public safety.~~

(4) Antibiotic preparations, including those medically important antimicrobial drugs federally labeled for over the counter sale listed in Appendix A of the federal Food and Drug Administration’s Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended~~.~~*;*

(5) Type A Medicated Articles as defined in Section 558.3(b)(2) of Title 21 of the Code of Federal Regulations *(4-1-18), which is hereby incorporated by reference, and*

(6) Any drug that has a withdrawal period.

~~(g) “Restricted livestock drug licensee” is a person that has obtained a restricted livestock drug license pursuant to Article 5 (commencing with Section 14321) of Chapter 4 of Division 7 of the Food and Agricultural Code.~~

(j) "Restricted livestock drug licensee" is a ~~firm that has obtained a restricted livestock drug license~~ *location licensed* pursuant to *Article 3 of Chapter 1 of Division 5 of Title 3 of the California Code of Regulations* ~~Article 5 (commencing with Section 14321) of Chapter 4 of Division 7 of the Food and Agricultural Code~~ *where sales of restricted livestock drugs occur*.

~~(h) "Veterinary feed directive" has the same definition as in Section 558.3 of Title 21 of the Code of Federal Regulations.~~

~~(i) "Veterinary prescription" means a lawful non-verbal order, given by a licensed veterinarian, for use of a medically important antimicrobial drug.~~

Note: Authority Cited: Sections 407, 14231, 14403~~,~~ and 14405~~, of the~~ Food and Agricultural Code. Reference: Section~~s~~ 14203, 14321, 14400, 14403 and 14405~~, of the~~ Food and Agricultural Code~~.; Section 4036 of the Business and Professions Code; Section 503(f) of the federal Food, Drug, and Cosmetic Act~~.

ARTICLE 2. GENERAL PROVISIONS

§5008 ~~5006~~. Sales of ~~Medically Important Antimicrobial~~ *California Prescription* Drugs.

~~(a) Notwithstanding Sections 14401 and 14402 of the Food and Agricultural Code and Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, medically important antimicrobial drugs may be sold by retailers licensed pursuant to Article 5 (commencing with Section 14321) of Chapter 4 of Division 7 of the Food and Agricultural Code with a prescription or veterinary feed directive from a licensed veterinarian.~~

~~(b) Medically important antimicrobial drugs are a subset of the broader classification of restricted livestock drugs under Section 14203(d) of the Food and Agricultural Code and are therefore subject to Chapter 4 of Division 7 of the Food and Agricultural Code and Chapter 1 of Division 5 of Title 3 of the of the California Code of Regulations, in addition to Chapter 4.5 of Division 7 of the Food and Agricultural Code and the provisions of this chapter.~~

~~(c) Pursuant to Food and Agricultural Code Section 14262(d), a restricted livestock drug licensee shall not sell any drug that is required by federal law to be sold on prescription only unless they also hold a valid license under Chapter 9 of Division 2 of the Business and Professions Code allowing them to do so.~~

~~(d) The provisions of this chapter apply only to medically important antimicrobial drugs sold by restricted livestock drug licensees to the end user for the purpose of administration to livestock, rather than sales made to other businesses for the purpose of resale.~~

(a) The provisions of this chapter apply only to restricted livestock drug licensees that choose to sell California prescription drugs pursuant to Chapter 4.5 of Division 7 of the Food and Agricultural Code. These are restricted livestock drugs under Section 14203(d) of the Food and Agricultural Code and are therefore subject to Chapter 4 of Division 7 of the Food and Agricultural Code and Chapter 1 of Division 5 of Title 3 of the of the California Code of Regulations, in addition to Chapter 4.5 of Division 7 of the Food and Agricultural Code and the provisions of this chapter.

(b) ~~A restricted livestock drug licensee shall not sell federal prescription drugs. Pursuant to Food and Agricultural Code Section 14262(d), a~~ *A* restricted livestock drug licensee shall not sell any

drug that is required by federal law to be sold by prescription only unless ~~they~~ *the licensee* also holds a valid license under ~~Article 7 or Article 15 of Chapter 9 of Division 2~~ *Section 4110 or 4196* of the Business and Professions Code allowing ~~them~~ *it* to do so.

(c) A restricted livestock drug licensee shall only sell California prescription drugs to an end user for the sole purpose of administration to livestock. A restricted livestock drug licensee shall not sell a California prescription drug to another business for resale unless ~~they~~ *the licensee* also holds a valid license under ~~Article 11 of Chapter 9 of Division 2~~ *Section 4160* of the Business and Professions Code allowing ~~them~~ *it* to do so.

(d) A restricted livestock drug licensee shall not sell a California prescription drug until the information required in Section 5002(a)(2)(F) of Title 3 of the California Code of Regulations has been submitted to the Department.

Note: Authority Cited: Sections 407, 14231, 14403~~,~~ and 14405~~, of the~~ Food and Agricultural Code. Reference: Sections 14203, 14262, 14281, 14321~~,~~ and 14403~~, of the~~ Food and Agricultural Code~~; Articles 7, 11, and 15 of Chapter 9 of Division 2 *Sections 4110, 4160, and 4196* of the Business and Professions Code~~.

ARTICLE 3. ADDITIONAL REQUIREMENTS ~~FOR RETAIL SALES OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS~~

~~§5007. Verification.~~

~~(a) A restricted livestock drug licensee shall not sell a medically important antimicrobial drug at retail without the purchaser first providing a valid veterinary prescription or veterinary feed directive.~~

~~(b) A restricted livestock drug licensee shall verify that the veterinarian listed on a veterinary prescription or veterinary feed directive is currently licensed by the California Veterinary Medical Board prior to completing the retail sale of any medically important antimicrobial drug.~~

> ~~(1) For the purpose of veterinarian license verification, a restricted livestock drug licensee shall rely upon the information on the Department of Consumer Affairs' licensing and enforcement website.~~

~~(c) No medically important antimicrobial drug may be sold at retail by a restricted livestock drug licensee more than six months after the issuance date of a veterinary prescription or veterinary feed directive or after the expiration date listed on a veterinary prescription or veterinary feed directive, whichever comes first.~~

~~Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Section 14403 of the Food and Agricultural Code, Section 4830 of the Business and Professions Code, Section 558.6(b)(3)(v) of Title 21 of the Code of Federal Regulations, Section 1780.1(g)(2) of Title 16 of the California Code of Regulations.~~

~~§5008. Sales Records.~~

~~(a) In addition to the recordkeeping requirements for sales of restricted livestock drugs listed in Chapter 4 of Division 7 of the Food and Agricultural Code and Section 5004 of the California Code of Regulations, each restricted livestock drug licensee shall include the following~~

additional information in the record for each retail sale of a medically important antimicrobial drug:

(1) The name and California Veterinary Medical Board license number of the prescribing veterinarian.

(2) A unique transaction identification number. This number must be listed on the record of sale as well as on the corresponding copy of the veterinary prescription or veterinary feed directive maintained on file.

(3) A copy of the veterinary prescription or veterinary feed directive labeled with the corresponding unique transaction identification number.

(b) The record of each retail sale of a medically important antimicrobial drug and accompanying copy of the veterinary prescription or veterinary feed directive shall be kept by a restricted livestock drug licensee for a period of not less than three years following the retail transaction.

(c) The record of each retail sale of a medically important antimicrobial drug and accompanying copy of the veterinary prescription or veterinary feed directive is subject to audit by the Secretary and shall be made available to the Secretary upon request.

Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Sections 14295, 14328, 14329, 14330, 14403, 14405, and 14406 of the Food and Agricultural Code.

§5009. Storage and Inventory.

(a) Each restricted livestock drug licensee shall store medically important antimicrobial drugs in a secure, lockable area.

(b) Entry into areas where medically important antimicrobial drugs are held shall be limited to authorized personnel.

(c) Restricted livestock drug licensees shall establish, maintain, and adhere to written policies and training procedures for all employees that handle and dispense medically important antimicrobial drugs for retail sale and shall include the following:

(1) The receipt, security, storage, inventory, labeling, and dispensing of medically important antimicrobial drugs.

(2) Identifying, recording, and internally reporting losses or thefts of medically important antimicrobial drugs.

(3) Maintaining a correct inventory of medically important antimicrobial drugs and verifying that inventory records are free from errors and inaccuracies.

(4) Maintaining records to document proper storage conditions for medically important antimicrobial drugs as recommended by the manufacturer and required by regulation.

(d) All invoices and records of shipment for medically important antimicrobial drugs shall be kept on file and maintained for at least three years from the date of shipment.

~~(e) All invoices and records of shipment for medically important antimicrobial drugs are subject to audit by the Secretary and shall be made available to the Secretary upon request.~~

~~Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Sections 14295, 14327, 14330, 14403, and 14405 of the Food and Agricultural Code.~~

~~§5010. Labeling.~~

~~(a) A prescription for a medically important antimicrobial drug shall be dispensed in accordance with its federally approved label. If a medically important antimicrobial drug is to be administered off-label in accordance with a veterinarian prescription, it shall be dispensed by a restricted livestock drug licensee with an added label including all of the following:~~

~~(1) Date dispensed.~~

~~(2) Name and address of the prescribing veterinarian.~~

~~(3) Name of the client who was issued the veterinary prescription or veterinary feed directive.~~

~~(4) Established name of the medically important antimicrobial drug or, if formulated from more than one active ingredient, the established name of each ingredient.~~

~~(5) Class/species or identification of the animal or the herd, flock, pen, lot, or other group of animals being treated.~~

~~(6) Condition for which the medically important antimicrobial drug was prescribed.~~

~~(7) Directions for use, including dosage, frequency, route of administration, duration of treatment, and withdrawal time.~~

~~(8) Date of expiration.~~

~~(b) Upon receipt of a veterinary prescription or veterinary feed directive lacking sufficient information to fulfill the labeling requirements described in Section 5010(a), the restricted livestock drug licensee shall contact the prescribing veterinarian to obtain the required information prior to dispensing the medically important antimicrobial drug and shall document any such request for clarification.~~

~~Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Section 14330 and 14403 of the Food and Agricultural Code.~~

§5009. Qualified Individuals.

(a) Each restricted livestock drug licensee that chooses to sell California prescription drugs shall identify one (1) or more employees to serve as qualified individual(s) responsible for protecting the public health and safety in the handling, storage, and sale of California prescription drugs.

(b) A qualified individual shall be at least 18 years of age.

(c) A qualified individual shall complete a training program that meets the following:

(1) Offered by one of the following:

(A) Federal, state, or local government agencies~~,~~*;*

(B) ~~Accredited u~~*U*niversity or college *accredited by* a *regional or national accrediting agency recognized by the United States Department of Education~~,~~; or*

(C) ~~Accredited v~~*V*eterinarian technician program *accredited by the American Veterinary Medical Association's Committee on Veterinary Technician Education and Activities~~,~~.*

~~(D) American Veterinary Medical Association or affiliated state, local, or specialty organization; or~~

~~(E) Other third-party verified educational program verified by the Department of Food and Agriculture.~~

(2) Addresses each of the following subjects with regard to California prescription drugs:

(A) Applicable state and federal laws, including how to identify whether a product is a California prescription drug~~,~~*;*

(B) The importance and obligations relative to drug use on livestock, including public health threats such as residue hazards to consumers and antimicrobial resistance~~,~~*;*

(C) How to read and understand information contained on drug labels and package inserts, including cautionary statements and withdrawal times~~,~~*;*

(D) How to read and understand a prescription and verify that it is in accordance with the labeled use for the prescribed drug. This shall include information on terminology, abbreviations, dosages, and routes of administration for drugs prescribed by veterinarians~~,~~*; and*

(E) ~~United States Pharmacopoeia standards relating to the safe storage and handling of drugs.~~ *How to safely store and handle California prescription drugs in accordance with the storage conditions indicated on the manufacturer's label.*

(d) Alternatives to the training requirements specified in paragraph (c) of this section include fulfillment of one of the following:

(1) ~~Possessing a r~~*R*egistration as a registered veterinary technician with the California Veterinary Medical Board~~,~~*;*

(2) ~~Being eligible~~ *Eligibility* to take the State Board of Pharmacy's pharmacist licensure exam*ination* or the *California* Veterinary Medical Board's veterinarian licensure examination~~,~~*; or*

(3) Possess*ion*~~ing a license as a~~*of a* pharmacist *license issued by* ~~with~~ the State Board of Pharmacy.

Note: Authority Cited: Sections 407, 14231, 14403~~,~~ and 14405~~, of the~~ Food and Agricultural Code. Reference: Section 14403~~, of the~~ Food and Agricultural Code~~; Section 4053, of the Business and Professions Code; Section 1780.1 of Title 16 of the California Code of Regulations~~.

§5010. Sale Requirements.

(a) A California prescription drug shall only be sold by a qualified individual.

(b) A qualified individual shall not sell a California prescription drug without the purchaser first providing a prescription in a written, facsimile, or electronic image format. A qualified individual shall not alter or amend a prescription nor sell a California prescription drug on the basis of an oral order. ~~A qualified individual shall not alter or amend any prescription.~~ Prior to selling the *California* prescri*ption*~~bed~~ drug, the qualified individual shall verify:

(1) The prescription ~~document must~~ describe*s* a use that is in accordance with the manufacturer or distributor's label for the prescribed drug~~,~~*; and*

(2) The date sold is within the expiration date and within six months of the issuance date listed on the prescription.

(c) In addition to the recordkeeping requirements listed in Chapter 4 of Division 7 of the Food and Agricultural Code and Section 5004 of Title 3 of the California Code of Regulations, a restricted livestock drug licensee shall comply with the following provisions for each sale of a California prescription drug.

(1) Include *all of* the following in the record of sale:

(A) Indication that the drug sold is a California prescription drug~~.~~*;*

(B) Identification of the qualified individual selling the drug~~.~~*; and*

(C) A unique ~~transaction~~ identification number.

(2) Retain a copy of the prescription labeled with the corresponding unique ~~transaction~~ identification number listed in the record of sale.

(3) The record of sale and copy of the prescription:

(A) Shall be retained for a period of not less than three (3) years following the ~~transaction~~ *date of sale*.

(B) Are subject to audit by the *Department* ~~Secretary~~ and shall be made available to the ~~Secretary~~ *Department* upon request.

Note: Authority Cited: Sections 407, 14231, 14403~~,~~ and 14405~~, of the~~ Food and Agricultural Code. Reference: Sections 14295, 14327, 14328, 14329, 14330, 14358, 14403~~,~~ and 14405~~, of the~~ Food and Agricultural Code~~; Sections 4053 and 4105 of the Business and Professions Code; Section 558.6(b)(3)(v) of Title 21 of the Code of Federal Regulations; Section 1780.1 of Title 16 of the California Code of Regulations~~.

§5011. Storage and Inventory Requirements.

(a) Each restricted livestock drug licensee shall store California prescription drugs in a secure, lockable area that shall only be accessible to the qualified individual(s) identified to the Department *pursuant to section 5002(a)(2)(F) or section 5002(e) of Title 3 of the California Code of Regulations*.

(b) Each restricted livestock drug licensee shall maintain on the premises fixtures and equipment in a clean and orderly condition. ~~The premises shall be dry, well-ventilated, and have adequate lighting. Temperature and humidity monitoring shall be conducted to assure compliance with the most recent version of the United States Pharmacopeia Standards.~~ *California prescription drugs shall be stored in accordance with the storage conditions indicated on the manufacturer's label.*

(c) No restricted livestock drug licensee shall sell a California prescription drug except in the container in which it is packaged by the manufacturer or distributor.

(1) A restricted livestock drug licensee may break down case lots of *California prescription* drugs, so long as the seals on the individual containers are not broken.

(2) A restricted livestock drug licensee shall not open an individual container and count out or measure out any quantity of California prescription drugs.

(d) Each restricted livestock drug licensee shall adhere to the following procedures for handling damaged or outdated California prescription drugs:

(1) California prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are *disposed of in the manner indicated the written procedures developed in accordance with Section 5012*~~returned to their supplier or properly disposed of~~.

(2) Any California prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other drugs until they are *disposed of in the manner indicated the written procedures developed in accordance with Section 5012*~~returned to their supplier or properly disposed of~~.

(e) Each restricted livestock drug licensee shall maintain an inventory of California prescription drugs, shall verify that inventory records are free from errors and inaccuracies, and shall identify~~,~~ *and* record~~, and internally report~~ losses or thefts of California prescription drugs.

(f) All records related to the receipt, storage, inventory, sale, and disposition of California prescription drugs:

(1) Shall be retained for a period of not less than three (3) years from the date of *creation* ~~making~~.

(2) Are subject to audit by the *Department* ~~Secretary~~ and shall be made available to the *Department* ~~Secretary~~ upon request.

Note: Authority Cited: Sections 407, 14231, 14403~~,~~ and 14405~~, of the~~ Food and Agricultural Code. Reference: Sections 14295, 14327, 14330, 14358~~,~~ and 14403~~, of the~~ Food and

Agricultural Code~~; Sections 4105 and 4197 of the Business and Professions Code; Sections 1780 and 1780.1 of Title 16 of the California Code of Regulations~~.

§5012. Written Operating Procedures.
(a) Each restricted livestock drug licensee shall establish, maintain, and adhere to store-specific written operating procedures for the receipt, storage, inventory, sale, and disposition of California prescription drugs ~~by qualified individuals~~.

(b) Each qualified individual employed by a restricted livestock drug licensee shall receive training on the licensee's store-specific written operating procedures.

(c) All records pertaining to this section:

(1) Shall be retained for a period of not less than three (3) years from the date of *creation* ~~making~~ or after a qualified individual's last date of employment.

(2) Are subject to audit by the *Department* ~~Secretary~~ and shall be made available to the *Department* ~~Secretary~~ upon request.

Note: Authority Cited: Sections 407, 14231, 14403~~,~~ and 14405~~. of the~~ Food and Agricultural Code. Reference: Sections 14295, 14327, 14330, 14403~~,~~ and 14405~~. of the~~ Food and Agricultural Code~~; Section 4198 of the Business and Professions Code; Section 1780 of Title 16 of the California Code of Regulations~~.

§5013. Pharmacist Oversight.
(a) Each restricted livestock drug licensee shall either retain a consulting pharmacist or employ a pharmacist on staff.

(b) If a restricted livestock drug licensee chooses to retain a consulting pharmacist, the consulting pharmacist shall *complete the following on a quarterly basis:*

~~(1) Conduct an inspection of the restricted livestock drug licensee quarterly.~~

~~(2)~~(1) ~~Develop, r~~*R*eview, approve, and revise the restricted livestock drug licensee's store-specific written operating procedures *as defined in Section 5012(a) of this chapter*.

(2) Ensure the restricted livestock drug licensee is following all written procedures and is maintaining all records required pursuant to Sections 5004 and 5011(e).

(3) Issue a signed, written certification stating whether or not the restricted livestock drug licensee is operating in compliance with California law and regulations regarding California prescription drugs.

~~(4)~~ *(c)* ~~If a restricted livestock drug licensee is not in compliance, the consulting pharmacist shall notify the Department within ten (10) days.~~ *The consulting pharmacist shall notify the Department within ten (10) days if the restricted livestock drug licensee is not in compliance with California law and regulations regarding California prescription drugs.*

(~~c~~d) If a restricted livestock drug licensee chooses to employ a pharmacist on staff, the staff pharmacist shall:

(1) ~~Develop, r~~*R*eview, approve, and revise the restricted livestock drug licensee's store-specific written operating procedures *as defined in Section 5012(a) of this chapter*.

(2) Ensure the restricted livestock drug licensee is *following all written procedures and is maintaining all records required pursuant to Sections 5004 and 5011(e)*~~operating in compliance with California law and regulations regarding California prescription drugs~~.

(3) A pharmacist employed by a restricted livestock drug licensee shall be exempt from the following provisions of this chapter:

(A) Prohibition on the sale of a California prescription drug on the basis of an oral order~~,~~ *as specified in* Section 5010(b).

(B) Prohibition on the sale of a California prescription drug for an extralabel use~~,~~ *as specified in* Section 5010(b)(1).

(d) The restricted livestock drug licensee shall disclose to the Department if the consulting or staff pharmacist has an ownership or financial interest in the ~~firm~~ *location*.

(e) All records pertaining to this section:

(1) Shall be retained for a period of not less than three (3) years from the date of *creation* ~~making~~.

(2) Are subject to audit by the *Department* ~~Secretary~~ and shall be made available to the *Department* ~~Secretary~~ upon request.

Note: Authority Cited: Sections 407, 14231, 14403~~,~~ and 14405~~. of the~~ Food and Agricultural Code. Reference: Sections 14295, 14327, 14330, 14403~~,~~ and 14405~~. of the~~ Food and Agricultural Code~~; Section 4198 of the Business and Professions Code; Section 1780 of Title 16 of the California Code of Regulations~~.

ARTICLE 4. VIOLATIONS AND PENALTIES

§5014 ~~5011~~. Violations.

~~(a) It is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug that is required by federal law to be sold on prescription only unless they also hold a valid license under Chapter 9 of Division 2 of the Business and Professions Code allowing them to do so.~~

~~(b) It is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug at retail unless the purchaser provides a valid veterinary prescription or veterinary feed directive.~~

~~(c) It is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug at retail if the veterinary prescription or veterinary feed directive provided by the purchaser is not issued by a veterinarian licensed by the California Veterinary Medical Board.~~

~~(d) It is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug at retail beyond the expiration date listed on the veterinary prescription or veterinary feed directive or if the date of issuance of the veterinary prescription or veterinary feed directive is more than six months prior to the date of purchase.~~

~~(e) It is unlawful for any restricted livestock drug licensee to prevent the entry into and inspection of any premises where medically important antimicrobial drugs are stored or sold.~~

~~(f) It is unlawful for any restricted livestock drug licensee to fail to keep adequate retail sales records of medically important antimicrobial drugs or to fail to make the required records available to the Secretary upon request as required by Section 5008 of this chapter.~~

~~(g) It is unlawful for any restricted livestock drug licensee to fail to comply with the minimum standards for storage and inventory of medically important antimicrobial drugs as required by Section 5009 of this chapter.~~

~~(h) It is unlawful for any restricted livestock drug licensee to fail to comply with the minimum standards for labeling medically important antimicrobial drugs sold at retail as required by Section 5010 of this chapter.~~

~~Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Sections 14203, 14262, 14295, 14321, 14327, 14328, 14329, 14330, 14403, 14405, and 14406 of the Food and Agricultural Code, Section 4830 of the Business and Professions Code, Section 558.6(b)(3)(v) of Title 21 of the Code of Federal Regulations, Section 1780.1(g)(2) of Title 16 of the California Code of Regulations.~~

(a) It is unlawful for any *business* ~~restricted livestock drug licensee~~ to sell any drug that is required by federal law to be sold on prescription only unless the~~y~~ *business* also holds a valid license under Article 7 or Article 15 of Chapter 9 of Division 2 of the Business and Professions Code allowing them to do so.

(b) It is unlawful for any *business* ~~restricted livestock drug licensee~~ to sell any California prescription drug to another business for resale unless the~~y~~ *business* also holds a valid license under Article 11 of Chapter 9 of Division 2 of the Business and Professions Code allowing them to do so.

(c) It is unlawful for any employee of a restricted livestock drug licensee to sell a California prescription drug unless they are a qualified individual that meets the requirements of Section 5009 of this chapter that has been identified to the Department at the time of licensure, renewal, or upon appointment.

(d) It is unlawful for any qualified individual to sell any California prescription drug at retail unless the purchaser provides a valid prescription issued by a veterinarian.

(e) It is unlawful for any qualified individual to alter or amend any prescription.

(f) It is unlawful for any qualified individual who is not a licensed pharmacist to sell any California prescription drug on the basis of an oral order.

(g) It is unlawful for any qualified individual who is not a licensed pharmacist to sell any California prescription drug for a purpose that is not in accordance with its manufacturer or distributor's label.

(h) It is unlawful for any qualified individual to sell any California prescription drug at retail beyond the expiration date listed on the prescription or if the date of issuance of the prescription is more than six months prior to the date of purchase.

(i) It is unlawful for any restricted livestock drug licensee to fail to keep ~~adequate~~ sales records of California prescription drugs or to fail to make the required records available to the *Department* ~~Secretary~~ upon request as required by Section 5010 of this chapter.

(j) It is unlawful for any restricted livestock drug licensee to fail to comply with the minimum standards for receipt, storage, inventory, sale, and disposition of California prescription drugs as required by Section 5011 of this chapter.

(k) It is unlawful for any qualified individual to sell any California prescription drug except in the container in which it is packaged by the manufacturer or distributor.

(l) It is unlawful for any qualified individual to sell any California prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated.

(m) It is unlawful for any restricted livestock drug licensee to fail to comply with the minimum standards for written operating procedures for sales of California prescription drugs as required by Section 5012 of this chapter.

(n) It is unlawful for any restricted livestock drug licensee to sell California prescription drugs without either retaining a consulting pharmacist or employing a pharmacist on staff as required by Section 5013 of this chapter.

(o) It is unlawful for any *business* ~~restricted livestock drug licensee~~ to prevent the entry into and inspection of any premises where California prescription drugs are stored or sold.

Authority Cited: Sections 407, 14231, 14403~~,~~ and 14405~~, of the~~ Food and Agricultural Code. Reference: Sections 14203, 14262, 14281, 14295, 14321, 14327, 14328, 14329, 14330, 14358, 14403~~,~~ and 14405~~, of the~~ Food and Agricultural Code~~; Sections 4053, 4105, 4197, and 4198 of the Business and Professions Code; Section 558.6(b)(3)(v) of Title 21 of the Code of Federal Regulations; Sections 1780 and 1780.1 of Title 16 of the California Code of Regulations~~.

§5015 ~~5012~~. Penalties.

(a) Upon finding a violation, the *Department* ~~Secretary~~ *shall* ~~may~~ issue a notice of warning *in accordance with Section 14408 Food and Agricultural Code*.

(b) A person who violates this chapter shall be liable for a civil penalty of two hundred and fifty dollars ($250) for each day a violation occurs ~~if at least one notice of warning has been issued by the Secretary for a prior violation within the preceding 12-month period~~.

(c) For a second or subsequent violation, a person who violates this chapter shall be punishable by an administrative fine, levied by the Secretary, in the amount of five hundred dollars ($500) for each day a violation occurs.

(d) A person may contest a penalty or fine for any violation specified in Section 5014 5011 by requesting an informal hearing before the Secretary. At the hearing, the person shall be given the right to present evidence on his or her own behalf.

(1) Requests must be submitted by written correspondence to the Secretary of the Department of Food and Agriculture Legal Office of Hearings and Appeals, 1220 "N" Street, Room A-107Suite 315, Sacramento, California 95814.

(2) Requests must be submitted within 30 days from the date of the notice of penalty or fine the notice of penalty or fine was signed by investigator and person notified.

(3) Requests must be accompanied by a written statement supporting the need for the hearing.

(4) A formal or informal hearing may be requested. The hearing officer shall determine whether to proceed with an informal hearing or whether a formal hearing or other appropriate administrative proceeding may be required by statute pursuant to Chapter 5 (commencing with section 11500), Part 1, Division 3, Title 2 of the Government Code.

(3 5) If a hearing is not requested, the penalty or fine shall constitute a final, and non-reviewable order.

(e) The Secretary may, after a hearing, refuse to issue or renew, or may suspend or revoke a restricted livestock drug license for any violation of this chapter, pursuant to the procedural requirements outlined in Section 14382 of the Food and Agricultural Code and Government Code Title 2, Division 3, Part 1, Chapter 5.

Note: Authority Cited: Sections 407, 14231, 14403, and 14405, of the Food and Agricultural Code. Reference: Sections 14382 and 14408, of the Food and Agricultural Code;, Division 3 Part 1 Chapter 5 of Title 2 of the Government Code. Chapter 4.5 (commending with Section 11400) and Chapter 5 (commencing with Section 11500) *Sections 11445.10, 11445.20, 11445.30, 11445.40, 11445.50, and 11445.60,* of the Government Code.